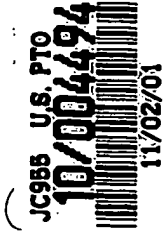


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

THE COMMISSIONER OF PATENTS AND TRADEMARKS

Washington, D.C. 20231

In re the application of: Yung-fu Chang  
For: EHRLICHIA CANIS GENES AND VACCINES  
Filed: November 2, 2001  
Application No.:  
Art Unit:  
Attorney Docket No.: CRF-2322 CIP



INFORMATION DISCLOSURE STATEMENT

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this information Disclosure Statement

1. ☒ Preliminary Statements
2. ☒ FORM PTO - 1449 (Modified)
3. ☐ Statement As To Information Material To Examination Not Found in Patents or Publications
4. ☒ Identification of Prior Application In Which Listed Information Was Already Cited and For Which No Copies Are Submitted Or Need Be Submitted.
5. ☐ Cumulative patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items.
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Certification under MPEP 609(e)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

[X] Express Mail No: EL 637<sup>586</sup>188 CERTIFICATE OF MAILING Date: 11/2/01

I hereby certify that this correspondence is being deposited with the United States Postal Service, return receipt requested in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on this date.

Judy H. Barron  
Judy H. Barron

## **Section 1. Preliminary statements**

Applicant submits herewith patents, publications or other information of which he is aware, which he believes may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR 1.56.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 CFR 1.56(g)), an admission that the information cited is, or is considered to be, material to patentability or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

## **Section 2. Form PTO - 1449 (Modified) (SEE ATTACHMENT)**

\*EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw a line through citation if not in conformance or not considered. Include a copy of this form with the next communication to applicant.

## **Section 3. Statement As To Information Material For Examination Not Found in Patents or Publications (Information not listed in PTO 1449)**

## **Section 4. Identification of Prior Application in Which Listed Information Was Already Cited and For Which No Copies Are Submitted Or Need Be Submitted**

09/358,322

07/21/99 (Items AA-AC; AD-BN; BO-BS and BT-BW already submitted)

## **Section 5. Cumulative Patents or Publications**

☐ Item(s)

are cumulative of the following patents or publication listed on Form PTO 1449 (modified):

In accordance with 37 CFR 1.98(c) a copy of \_\_\_\_\_ is being submitted with this information disclosure statement.

## **Section 6. Copies of Listed Information Items Accompanying This Statement**

Legible copies of all items listed accompany this information statement.

☐ Exception(s) to above:

☐ Items in prior application from which an earlier filing date is claimed for this application as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

## **Section 7. Concise Explanation of Non-English Language Listed Information Items**

## **Section 8. Translation(s) of Non-English Language Documents**

☐ Submitted herewith is an English translation of the following foreign language patents, publications or information or of those portions of those patents, publications or information considered to be material:

☐ No English language translations of the foreign language patents, publications or information or parts thereof are readily available, except for those listed above.

☐ The following foreign language documents submitted are believed to be the equivalent or substantial equivalent of the English language documents identified below, which are also submitted herewith.

**Section 9. Certification under Rule 1.97**

☐ The undersigned hereby certifies that:

a. This Statement is being filed after the latest of (1) three months after the filing date of a national application; (2) three months after the date of entry of the national stage as set forth in w 1.491 in an international application; (3) the mailing date of a first Office action on the merits.

b. The fee set forth in §1.17(p)

☐ Is being paid with this Information Disclosure Statement

☐ Is not due because:

☐ (1) Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the statement, or

☐ (2) No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the statement.

**Section 10. IDENTIFICATION OF PERSON(S) MAKING THIS INFORMATION DISCLOSURE STATEMENT**

The person making this statement is

(a) ☐ the inventor(s) who signs below

(b) ☒ the attorney who signs below on the basis of:

☐ the information supplied by the inventor(s)

☐ an individual associated with the filing and prosecution of this application (37 CFR 1.56(c)).

☒ the information in the attorney's file

  
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FORM PTO-1449 U.S. DEPT. OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO. CRF-2322	SERIAL NO. 10/004,494
	APPLICANT CHANG	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE 7/21/99	GROUP 1632

## U.S. PATENT DOCUMENTS

Exam Initial		DOCUMENT NUMBER	DATE	PATENTEE	CLASS	SUB	FILING DATE IF APPROPR
✓	AA	5,192,679	3/9/93	Dawson, J.E. et al.	435	243	
	AB	5,401,656	3/28/95	Dawson, J.E.	435	243	
	AC	5,413,931	5/9/95	Dawson, J.E.	435	252.1	
	A						

## FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

Exam Initial		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB	TRANSLATION YES   NO
	A						

## OTHER PRIOR ART

Exam Initial		Author, Title, Date, Pertinent Pages, Etc
	AD	Althchul, S.F. et al, 1990, "Basic local alignment search tool", J. Mol. Biol. 215: 403-410.
	AE	Betsou, F. et al, 1995, "Cloning and sequence of the Bordetella bronchiseptica adenylate cyclase-hemolysin-encoding gene: comparison with the Bordetella pertussis gene", Gene 162: 165-166.
	AF	Breitschwerdt, E.B. et al, 1998, "Doxycycline hyclate treatment of experimental canine Ehrlichiosis followed by challenge inoculation with two Ehrlichia canis strains", Antimicrobial Agents and Chemotherapy 42(2): 362-368.
	AG	Chang, Y.F. et al, 1987, "Identification and characterization of the Pasteurella haemolytica Leukotoxin", Infect. Immun. 55: 2348-2354.
	AH	Chang, Y. F. et al, 1989a, "Secretion of the Pasteurella leukotoxin by E. coli", FEMS Microbiology Let. 60: 169-174.
	AI	Chang, Y. F. et al, 1989b, "Cloning and Characterization of a hemolysin gene from Actinobacillus (Haemophilus) pleuropneumoniae", DNA 8(9): 635-647.
	AJ	Chang, Y. F. et al, 1993a, "Molecular characterization of a leukotoxin gene from a Pasteurella haemolytica-like organism, encoding a new member of RTX family", Infect. Immun. 61:2089-2095.
	AK	Chang, Y.F. et al, 1993b, "Molecular analysis of the Actinobacillus pleuropneumoniae RTX toxin-III gene cluster", DNA and Cell Biol. 12: 351-362.
	AL	Chang, Y.F. et al, 1993c, "Expression and secretion of outer surface protein (OspA) of Borrelia burgdorferi from E. coli", FEMS Microbiol. Lett. 109: 297-302.
	AM	Chang, Y.F. et al, 1995, "Recombinant OspA protects dogs against infection and disease caused by Borrelia burgdorferi", Infect. Immun. 63:3543-3549.
	AN	Dawson et al, 1991, "Serologic diagnosis of human Ehrlichiosis using two Ehrlichia canis isolates", Journal of Infectious Diseases 163: 564-567.
	AO	Degen, et al, 1986, "The human tissue plasminogen activator gene", Journal of Biological Chemistry 261(15): 6972-6985.

not provided

Joe Waites 1/18/05

AP	Donnelly et al, 1993, "Targeted delivery of peptide epitopes to class I major histocompatibility molecules by a modified <i>Pseudomonas</i> exotoxin", <i>Proc. Natl. Acad. Sci. USA</i> 90: 3530-3534.
AQ	Dumler et al, 1992, "Cell-mediated immune responses of adults to vaccination, challenge with <i>Rickettsia rickettsii</i> , or both", <i>Am. J. Trop. Med. Hyg</i> 46(2): 105-115.
AR	Goldman, L.A. et al, 1996, "Modifications of vectors pEF-BOS, pcDNA1 and pcDNA3 result in improved convenience and expression", <i>BioTechniques</i> 21: 1013-1015.
AS	Guermonprez, P.D. et al, 1999, "Direct delivery of the <i>Bordetella pertussis</i> adenylate cyclase toxin to the MHC class I antigen presentation pathway", <i>J. Immunol.</i> 162: 1910-1916.
AT	Gupta, R.K. and Siber, G.R., 1995, "Adjuvants for human vaccines: current status, problems and future prospects", <i>Vaccine</i> 13(14): 1263-1276.
AU	Harrus, et al., 1998, "Amplification of Ehrlichia/DNA from dogs 34 months after infection with <i>Ehrlichia canis</i> ", <i>Journal of Clinical Microbiology</i> 36(1): 73-76.
AV	Keysary et al, 1996, "The first isolation, in vitro propagation, and genetic characterization of <i>Ehrlichia canis</i> in Israel", <i>Veterinary Parasitology</i> 62: 331-340.
AW	Klinman, D. M. et al, 1997, "CpG motifs as immune adjuvants", <i>Vaccine</i> . 17:19-25.
AX	Launois et al, 1994, "T-cell epitope mapping of the major secreted myobacterial antigen Ag85A in tuberculosis and leprosy", <i>Infection and Immunity</i> 62(9): 3679-3687.
AY	Lee, B. and Horwitz, M.A, 1999, "T-cell epitope mapping of the three most abundant extracellular proteins of <i>Myobacterium tuberculosis</i> in outbred guinea pigs", <i>Infection and Immunity</i> 67(5): 2665-2670.
AZ	Nyika, A. et al, 1998, "A DNA vaccine protects mice against the rickettsial agent <i>Cowdria ruminantium</i> ", <i>Parasite Immunol.</i> 20:111-119.
BA	Rikihisa et al, 1992, "Analyses of <i>Ehrlichia canis</i> and a canine granulocytic <i>Ehrlichia</i> infection", <i>Journal of Clinical Microbiology</i> 30(1): 143-148.
BB	Robinson, H.L, 1997, "Nucleic acid vaccines: an overview", <i>Vaccine</i> 15(8): 785-787.
BC	Sebo, P. C. et al, 1995, "Cell-invasive activity of epitope-tagged adenylate cyclase of <i>Bordetella pertussis</i> allows in vitro presentation of a foreign epitope to CD8 <sup>+</sup> cytotoxic T cells", <i>Infect. Immun.</i> 63:3851-3857.
BD	Stewart, G.S. et al, 1986, "pHG165: A pBR322 copy number derivation of pUC8 for cloning and expression", <i>Plasmid</i> 15:172-186.
BE	Storey, J.R. et al 1998, "Molecular cloning and sequencing of three granulocytic <i>Ehrlichia</i> genes encoding high-molecular-weight immunoreactive proteins", <i>Infection and Immunity</i> 66(4): 1356-1363.
BF	Uetsuki et al, 1989, "Isolation and characterization of the human chromosomal gene for polypeptide chain elongation factor-1 $\alpha$ ", <i>Journal of Biological Chemistry</i> 264(10): 5791-5798.
BG	Wen et al, 1997, "Comparison of nested PCR with immunofluorescent-antibody assay for detection of <i>Ehrlichia canis</i> infection in dogs treated with doxycycline", <i>Journal of Clinical Microbiology</i> 35(7): 1852-1855.
BH	White, A. P. et al, 1999, "High efficiency gene replacement in <i>Salmonella enteritidis</i> : chimeric fimbrins containing a T-cell epitope from <i>Leishmania major</i> ", <i>Vaccine</i> 17: 2150-2161.
BI	Yuk, M.H. et al, 1998, "The BvgAS virulence control system regulates type III secretion in <i>Bordetella bronchiseptica</i> ", <i>Mol. Microbiol.</i> 28:945-959.
BJ	Cotter, P.A. and Miller, J.F., 1994, "BvgAS-mediated signal transduction: analysis of phase-locked regulatory mutants of <i>Bordetella bronchiseptica</i> in a rabbit model", <i>Infect. Immun.</i> 62: 3381-3390.
BK	Fayolle et al, 1996, "In vivo induction of CTL responses by recombinant adenylate cyclase of <i>Bordetella pertussis</i> carrying viral CD8 <sup>+</sup> T cell epitopes", <i>J. Immun.</i> 156:4697-4706.
BL	Fynan et al, 1993, DNA Vaccines: protective immunizations by parenteral, mucosal and gene-gun inoculations" <i>Proc. Natl Acad. Sci USA</i> 90:11478-11482.
BM	Gish, W. et al, 1993, "Identification of protein coding regions by database similarity", <i>Natural Genetics</i> 13: 266-272.
BN	Chen et al, 1994, "Identification of the antigenic constituents of <i>Ehrlichia chaffeensis</i> ", <i>Am. J. Tropic. Med. Hyg.</i> 50: 52-58.

EXAMINER	DATE CONSIDERED

not provided

FORM PTO-1449 U.S. DEPT. OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO. CRF-2322	SERIAL NO. 09/358,322
	APPLICANT Chang	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE 7/21/99	GROUP 1633

U.S. PATENT DOCUMENTS

Exam Initial		DOCUMENT NUMBER	DATE	PATENTEE	CLASS	SUB	FILING DATE IF APPROPR

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

Exam Initial		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB	TRANSLATION YES   NO
	BO	WO 98 42743 A	10/1/98	Europe			
	BP	WO 98 16554 A	4/23/98	US			
	BQ	WO 99 13720 A	3/25/99	US			

OTHER PRIOR ART

Exam Initial		Author, Title, Date, Pertinent Pages, Etc
	BR	Waghela, S.D. et al, 1991, "A cloned DNA probe identified Cowdria ruminantium in Amblyomma variegatum ticks", Jnl of Clinical Microbiology, vol. 29, n. 11, pgs 2571-2577
	BS	EMBL, Heidelberg, Germany; I40883, August 16, 1996, Abstract
EXAMINER		DATE CONSIDERED

not  
provided

FORM PTO-1449 U.S. DEPT. OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO. CRF-2322	SERIAL NO. 09/358,322
	APPLICANT Chang	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE 7/21/99	GROUP 1632

## U.S. PATENT DOCUMENTS

Exam Initial		DOCUMENT NUMBER	DATE	PATENTEE	CLASS	SUB	FILING DATE IF APPROPR
	A						
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## FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

Exam Initial		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB	TRANSLATION YES   NO
	A						
	A						
	A						

## OTHER PRIOR ART

Exam Initial		Author, Title, Date, Pertinent Pages, Etc
	BT	Freilberg, C. et al, 1997, Molecular basis of symbiosis between <i>Rhizobium</i> and legumes", Nature, Vol 387, pp 384-401
	BU	Springer, A. et al, 1996, Characterization and Nucleotide Sequence of pqqE and pqqF in <i>Methlobacterium extorquens</i> AM1, Journal of Bacteriology, pp 2154-2157.
	BV	DATABASE EMPRO1, Yamane, K. et al, 1997, "The 25 degrees region of the Bacillus subtilis chromosome determination of the sequence of a 146kb segment and identification of 113 genes", 1 page.
	BW	DATABASE EMPRO1, Andersson, S.G. et al, 1998, "The genome of sequence of Rickettsia prowazekii and the origin of mitochondria", 1 page.

EXAMINER	DATE CONSIDERED

not provided

## Section 2. Form PTO - 1449 (Modified) (ATTACHMENT)

Page 5 of 5

FORM PTO-1449 U.S. DEPT. OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO. CRF-2322 CIP	SERIAL NO.
	APPLICANT Chang	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE 11-2-01	GROUP

## U.S. PATENT DOCUMENTS

Exam Initial		DOCUMENT NUMBER	DATE	PATENTEE	CLASS	SUB	FILING DATE IF APPROPR
9w	CA	6,043,085	03/28/00	Yu, et al	435		

## FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

Exam Initial		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB	TRANSLATION YES   NO

## OTHER PRIOR ART

Exam Initial		Author, Title, Date, Pertinent Pages, Etc
9w	CB	Appel, M.J. et al, 1993, Experimental Lyme Disease in Dogs Produces Arthritis and Persistent Infection; Jnl of Infectious Diseases, 167, pp 651-654.
9w	CC	Chang, Y. et al, 1998; Detection of human granulocytic ehrlichiosis agent and <i>Borrelia burgdorferi</i> in ticks by polymerase chain reaction, J. Vet. Diagn Invest. ; 10, pp 56-59.
9w	CD	Chang, Y. et al, 1998, Experimental infection of the human granulocytic ehrlichiosis agent in horses; Veterinary Para.; 78, ppp. 137-145.
9w	CE	Chang, Y. et al, 1995, Recombinant OspA protects Dogs against Infection and Disease Caused by <i>Borrelia burgdorferi</i> ; Infection and Immunity, pp. 3543-3549.
9w	CF	Altschul, S. et al; Results of Blast; <a href="http://www.ncbi.nlm.nih.gov/blast/Blast.cgi">http://www.ncbi.nlm.nih.gov/blast/Blast.cgi</a> , 9-14-01, 40 pages.

EXAMINER	DATE CONSIDERED
Joe Wadac	1/18/05